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EXAMINER	
STITZEL, DAVID PAUL	

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1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,677	ROHDEWALD ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Response, which was filed on July 26, 2006, in response to the Official Action dated January 26, 2006, is acknowledged.

Status of Claims

Claims 1-6 and 15 were canceled, and claims 7 and 12 were amended, by an amendment that accompanied the aforementioned Response. Claim 16 is drawn to a non-elected invention. As a result, claims 7-14 are therefore examined herein on the merits for patentability.

Statutory Double Patenting

1. The provisional statutory double patenting rejection of claims 7-11 and 12-15 under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 9-13 and 15-18, respectively, of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application) is hereby withdrawn in light of the instant claim amendments reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S).

Nonstatutory Double Patenting

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re*

Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned or assigned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, *those portions of the specification which provide support for the patent claims may also be examined and considered* when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

1. The non-statutory obviousness-type double patenting rejection of claims 7 and 12 as being unpatentable over conflicting claim 1 of U.S. Patent 6,565,851 (hereinafter the conflicting Rohdewald '851 patent) is hereby withdrawn in light of the instant claim amendments reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S).

2. The provisional non-statutory obviousness-type double patenting rejection of claims 7-15 as being unpatentable over conflicting claims 9-13 and 15-18 of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application) is hereby withdrawn in light of the instant claim amendments reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S).

3. Claims 7 and 12 of the instant application are rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claim 1 of U.S. Patent 6,565,851 (hereinafter the conflicting Rohdewald '851 patent) in view of U.S. Pre-Grant Patent Application Publication 2003/0064123 (hereinafter the Thompson '123 publication).

Claims 7 and 12 of the instant application are directed to a method of attaining enhanced sexual wellness in both sexes by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; a proanthocyanidin stimulator for stimulating said NOS enzyme; and dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors.

Claim 1 of the conflicting Rohdewald '851 patent teaches a method of relieving symptoms of erectile dysfunction by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide

(NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme.

The Rohdewald '851 patent does not explicitly teach incorporating DHEA or DHEA-S androgen precursors within said composition for use in relieving symptoms of erectile dysfunction, as claimed in claims 7 and 12 of the instant application.

However, the Thompson '123 publication teaches a method of increasing the sexual responsiveness of erectile tissue by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and DHEA or DHEA-S androgen precursors (abstract; [0001]-[0013]; [0016]; [0019]-0026]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Rohdewald '851 patent by incorporating DHEA or DHEA-S androgen precursors therein, so as to increase the sexual responsiveness of erectile tissue of the genitalia, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Rohdewald '851 patent, so as to potentiate the production of testosterone thereby enhancing sexual responsiveness to sexual stimulation, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]).

As a result, although claims 7 and 12 of the instant application are not identical to claim 1 of the conflicting Rohdewald '851 patent, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove.

4. Claims 7-15 of the instant application are provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claims 9-13 and 15-18 of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application) in view of U.S. Pre-Grant Patent Application Publication 2003/0064123 (hereinafter the Thompson '123 publication).

Claims 7 and 12 of the instant application are directed to a method of attaining enhanced sexual wellness in both sexes by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; a proanthocyanidin stimulator for stimulating said NOS enzyme; and dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors.

Claims 9-13 and 15-18 of the conflicting Rohdewald '742 application teaches a method of attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme.

The Rohdewald '742 application does not explicitly teach incorporating DHEA or DHEA-S androgen precursors within said composition for use in attaining enhanced sexual wellness, as claimed in claims 7-15 of the instant application.

However, the Thompson '123 publication teaches a method of increasing the sexual responsiveness of erectile tissue by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition

comprising: an arginine substrate for the NOS enzymatic production of NO; and DHEA or DHEA-S androgen precursors (abstract; [0001]-[0013]; [0016]; [0019]-0026]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Rohdewald '742 application by incorporating DHEA or DHEA-S androgen precursors therein, so as to increase the sexual responsiveness of erectile tissue of the genitalia, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Rohdewald '742 application, so as to potentiate the production of testosterone thereby enhancing sexual responsiveness to sexual stimulation, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]).

As a result, although claims 7-15 of the instant application are not identical to claims 9-13 and 15-18 of the conflicting Rohdewald '742 application, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7-14 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The aforementioned claims contain subject matter that was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, claims 7 and 12 of the instant application are drawn to a method of "attaining enhanced sexual wellness," however it does not appear as though the Applicants have set forth within the instant application an explicit definition, description, or explanation as to what constitutes "attaining enhanced sexual wellness." Furthermore, although claims 7 and 12 of the instant application are drawn to a method of "attaining enhanced sexual wellness of both sexes," the only two examples present within the instant application are both directed to treating "erectile dysfunction" in male humans by administering a composition according to the instant application. It is duly noted however, that the instant specification also states that upon administering a composition according to the instant application enhanced sexual responsiveness is achieved by enhancing male penile erections and female clitoral tumescence. Based on the aforementioned observations, it appears as though the claimed recitation of "attaining enhanced sexual wellness of both sexes" is in essence directed to increasing the sexual responsiveness of erectile tissue of the genitalia in both male and female humans by administering a composition according to the instant application. Claims 8-11 and 13-14, which are dependent upon and include all of the limitations of independent claims 7 and 12, respectively, are therefore likewise rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

1. The rejection of claims 7, 8, 12 and 13 under 35 U.S.C. § 102(b) as being anticipated by International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) is hereby withdrawn in light of the instant claim amendments reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 9-11, 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) in view of U.S. Patent 5,906,987 (hereinafter the Chwalisz '987 patent) is hereby withdrawn in light of the instant claim amendments reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S).

2. Claims 7-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) in view of U.S. Pre-Grant Patent Application Publication 2003/0064123 (hereinafter the Thompson '123 publication).

With respect to claims 7-14 of the instant application, the Shell '212 publication teaches a method of treating erectile dysfunction by increasing the sexual responsiveness and receptivity of erectile tissue of the genitalia in both male and female humans (page 2, lines 1, 2 and 6; page 4, lines 16-19; page 9, lines 2-4) via stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme (page 1, lines 15-17; page 2, lines 20-22; page 4, lines 9-11 and 16-19; page 5, lines 11-13; page 9, lines 1-12 and 19-21; page 10, lines 2 and 6-11; page 14, lines 7-27; page 15, lines 1-6; page 16, lines 12-30; page 17, lines 1-5 and 17-24).

With respect to claims 8 and 13 of the instant application, the Shell '212 publication teaches a method comprising administering a higher optimum daily dosage level of said composition then incrementally reducing the daily dosage thereof to a threshold daily dosage level sufficient to maintain an appreciable stimulation of NOS enzyme activity (page 14, lines 7-18).

With respect to claims 7-14 of the instant application, the Shell '212 publication does not explicitly teach incorporating dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors within said composition, as instantly claimed.

However, the Thompson '123 publication teaches a method of increasing the sexual responsiveness of erectile tissue by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and DHEA or DHEA-S androgen precursors (abstract; [0001]-[0013]; [0016]; [0019]-0026]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Shell '212

publication by incorporating DHEA or DHEA-S androgen precursors therein, so as to increase the sexual responsiveness of erectile tissue of the genitalia, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Shell '212 publication, so as to potentiate the production of testosterone thereby enhancing sexual responsiveness to sexual stimulation, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]).

3. Claims 7-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) in view of U.S. Patent 4,835,147 (hereinafter the Roberts '147 patent).

With respect to claims 7-14 of the instant application, the Shell '212 publication teaches a method of treating erectile dysfunction by increasing the sexual responsiveness and receptivity of erectile tissue of the genitalia in both male and female humans (page 2, lines 1, 2 and 6; page 4, lines 16-19; page 9, lines 2-4) via stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme (page 1, lines 15-17; page 2, lines 20-22; page 4, lines 9-11 and 16-19; page 5, lines 11-13; page 9, lines 1-12 and 19-21; page 10, lines 2 and 6-11; page 14, lines 7-27; page 15, lines 1-6; page 16, lines 12-30; page 17, lines 1-5 and 17-24).

With respect to claims 8 and 13 of the instant application, the Shell '212 publication teaches a method comprising administering a higher optimum daily dosage level of said composition then

incrementally reducing the daily dosage thereof to a threshold daily dosage level sufficient to maintain an appreciable stimulation of NOS enzyme activity (page 14, lines 7-18).

With respect to claims 7-14 of the instant application, the Shell '212 publication does not explicitly teach incorporating dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors within said composition, as instantly claimed.

However, the Roberts '147 patent teaches a method of ameliorating sexual dysfunction in both male and female humans, wherein said method comprises administering a daily dosage of DHEA or DHEA-S androgen precursors (abstract; column 1, lines 1-68; column 2, lines 1-28; claims 3-9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Shell '212 publication by incorporating therein the DHEA or DHEA-S androgen precursors of the Roberts '147 patent, so as to ameliorate sexual dysfunction and enhance the sexual responsiveness in both male and female humans, as reasonably suggested by the Roberts '147 patent (column 1, lines 6-15 and 55-62; column 2, lines 10-15). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Shell '212 publication, so as to promote a proper balance in ratio of testosterone to estrogen, thereby ameliorating sexual dysfunction and enhancing sexual responsiveness in both male and female humans, as reasonably suggested by the Roberts '147 patent (column 1, lines 13-15).

4. Claims 7-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over German Patent Application Publication DE19845314 (hereinafter the Rohdewald '314 publication) in view of U.S. Pre-Grant Patent Application Publication 2003/0064123 (hereinafter the Thompson '123 publication).

With respect to claims 7-14 of the instant application, the Rohdewald '314 publication teaches a method of treating erectile dysfunction in humans via stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme (page 2, lines 2-4 and 18-21; page 3, lines 6-10; page 4, lines 18-22; page 5, lines 9, 14, 15, 18-20 and 23-25; page 6, lines 1-4, 8, 9 and 17-23; page 7, lines 8, 11 and 14).

With respect to claims 7-14 of the instant application, the Rohdewald '314 publication does not explicitly teach incorporating dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors within said composition, as instantly claimed.

However, the Thompson '123 publication teaches a method of increasing the sexual responsiveness of erectile tissue by stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and DHEA or DHEA-S androgen precursors (abstract; [0001]-[0013]; [0016]; [0019]-0026]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Rohdewald '314 publication by incorporating DHEA or DHEA-S androgen precursors therein, so as to increase the sexual responsiveness of erectile tissue of the genitalia, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Rohdewald '314 publication, so as to potentiate the production of testosterone thereby enhancing sexual responsiveness to sexual stimulation, as

reasonably suggested by the Thompson '123 publication ([0007]; [0013]). One of ordinary skill in the art would have had a reasonable expectation of success in modifying the method and corresponding composition of the Rohdewald '314 publication by incorporating DHEA or DHEA-S androgen precursors therein, as reasonably suggested by the Thompson '123 publication ([0007]; [0013]), because while there are obvious differences in the sexual response between men and women, one common neurophysiological aspect of the sexual response in both males and females is the erectile response. Homologous with male penile erections, are female clitoral erections or female clitoral tumescence. The erectile response in both males and females results from the erectile tissue of the genitalia becoming engorged with blood in neurophysiological response to sexual stimulation, which activates nitric oxide synthase (NOS) enzyme and produces nitric oxide (NO) in both males and females.

With respect to claims 8 and 13 of the instant application, neither the Rohdewald '314 publication, nor the Thompson '123 publication explicitly teach administering an initial elevated daily dosage level of said composition then subsequently reducing the daily dosage thereof to a threshold daily dosage level sufficient to maintain an appreciable stimulation of NOS enzyme activity, as instantly claimed. However, while the aforementioned prior art references do not explicitly teach administering an initial elevated daily dosage level of said composition then subsequently reducing the daily dosage level thereof to a threshold daily dosage level that is sufficient to maintain an appreciable stimulation of NOS enzyme activity, it is well within the purview of the skilled artesian to determine the optimal initial loading daily dosage amount and the optimal maintenance daily dosage amount of said composition by systematically adjusting the dosage amounts thereof during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the dosage amounts of the initial loading phase and the

subsequent maintenance phase of administration of said composition during the course of routine experimentation so as to quickly obtain a desired serum level of said composition and thus stimulation of NOS enzyme activity, and then maintain said desired serum level and stimulation of enzymatic NOS activity during the remaining course or period of treatment. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

5. Claims 7-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over German Patent Application Publication DE19845314 (hereinafter the Rohdewald '314 publication) in view of U.S. Patent 4,835,147 (hereinafter the Roberts '147 patent).

With respect to claims 7-14 of the instant application, the Rohdewald '314 publication teaches a method of treating erectile dysfunction in humans via stimulating nitric oxide synthase (NOS) enzyme and producing nitric oxide (NO), wherein said method comprises administering a daily dosage of a composition comprising: an arginine substrate for the NOS enzymatic production of NO; and a proanthocyanidin stimulator for stimulating said NOS enzyme (page 2, lines 2-4 and 18-21; page 3, lines 6-10; page 4, lines 18-22; page 5, lines 9, 14, 15, 18-20 and 23-25; page 6, lines 1-4, 8, 9 and 17-23; page 7, lines 8, 11 and 14).

With respect to claims 7-14 of the instant application, the Rohdewald '314 publication does not explicitly teach incorporating dehydroepiandrosterone (DHEA) or dehydroepiandrosterone sulfate (DHEA-S) androgen precursors within said composition, as instantly claimed.

However, the Roberts '147 patent teaches a method of ameliorating sexual dysfunction in both male and female humans, wherein said method comprises administering a daily dosage of DHEA or DHEA-S androgen precursors (abstract; column 1, lines 1-68; column 2, lines 1-28; claims 3-9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method and corresponding composition of the Rohdewald '314 publication by incorporating therein the DHEA or DHEA-S androgen precursors of the Roberts '147 patent, so as to ameliorate sexual dysfunction and enhance the sexual responsiveness in both male and female humans, as reasonably suggested by the Roberts '147 patent (column 1, lines 6-15 and 55-62; column 2, lines 10-15).One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate DHEA or DHEA-S androgen precursors into the method and corresponding composition of the Rohdewald '314 publication, so as to promote a proper balance in ratio of testosterone to estrogen, thereby ameliorating sexual dysfunction and enhancing sexual responsiveness in both male and female humans, as reasonably suggested by the Roberts '147 patent (column 1, lines 13-15). One of ordinary skill in the art would have had a reasonable expectation of success in modifying the method and corresponding composition of the Rohdewald '314 publication by incorporating therein the DHEA or DHEA-S androgen precursors of the Roberts '147 patent, because while there are obvious differences in the sexual response between men and women, one common neurophysiological aspect of the sexual response in both males and females is the erectile response. Homologous with male penile erections, are female clitoral erections or female clitoral tumescence. The erectile response in both males and females results from the erectile tissue of the genitalia becoming engorged with blood in neurophysiological response to sexual stimulation, which activates nitric oxide synthase (NOS) enzyme and produces nitric oxide (NO) in both males and females.

With respect to claims 8 and 13 of the instant application, neither the Rohdewald '314 publication, nor the Roberts '147 patent explicitly teach administering an initial elevated daily dosage level of said composition then subsequently reducing the daily dosage thereof to a threshold daily dosage level sufficient to maintain an appreciable stimulation of NOS enzyme activity, as instantly claimed. However, while the aforementioned prior art references do not explicitly teach administering an initial elevated daily dosage level of said composition then subsequently reducing the daily dosage level thereof to a threshold daily dosage level that is sufficient to maintain an appreciable stimulation of NOS enzyme activity, it is well within the purview of the skilled artesian to determine the optimal initial loading daily dosage amount and the optimal maintenance daily dosage amount of said composition by systematically adjusting the dosage amounts thereof during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the dosage amounts of the initial loading phase and the subsequent maintenance phase of administration of said composition during the course of routine experimentation so as to quickly obtain a desired serum level of said composition and thus stimulation of NOS enzyme activity, and then maintain said desired serum level and stimulation of enzymatic NOS activity during the remaining course or period of treatment. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Remarks

The following are prior art patents made of record and considered pertinent to the Applicants' disclosure, but are not however currently relied upon in construing the claim rejections as set forth hereinabove:

- U.S. Patent 5,906,987 (the Chwalisz '987 patent) (column 4, lines 25-31, 51-54 and 60-67; column 8, lines 4-21; column 9, lines 20-25); and
- U.S. Patent 5,565,466 (the Gioco '466 patent) (column 4, lines 45-51).

Examiner's Response to Applicant's Remarks

Although Applicants' arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicant's claim amendments necessitated the new grounds of rejection as set forth hereinabove.

In light of Applicant's claim amendments to claims 7 and 12 reciting dehydroepiandrosterone (DHEA) and dehydroepiandrosterone sulfate (DHEA-S) as new claim limitations, the following rejections are moot in view of the new grounds of rejection:

1. The provisional statutory double patenting rejection of claims 7-11 and 12-15 under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 9-13 and 15-18, respectively, of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application) is hereby withdrawn in light of the instant claim amendments.

2. The non-statutory obviousness-type double patenting rejection of claims 7 and 12 as being unpatentable over conflicting claim 1 of U.S. Patent 6,565,851 (hereinafter the conflicting Rohdewald '851 patent) is hereby withdrawn in light of the instant claim amendments.

3. The provisional non-statutory obviousness-type double patenting rejection of claims 7-15 as being unpatentable over conflicting claims 9-13 and 15-18 of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application) is hereby withdrawn in light of the instant claim amendments.

4. The rejection of claims 7, 8, 12 and 13 under 35 U.S.C. § 102(b) as being anticipated by International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) is hereby withdrawn in light of the instant claim amendments.

5. The rejection of claims 9-11, 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO00/00212 (hereinafter the Shell '212 publication) in view of U.S. Patent 5,906,987 (hereinafter the Chwalisz '987 patent) is hereby withdrawn in light of the instant claim amendments.

Conclusion

Applicant's claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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